OCT 2 6 2000

K002577

Premarket Notification [510(K)] Summary
(per 21 CFR 807.92)

1. Submitted by:

MediVance, Inc.
500 S. Arthur Avenue, Suite 100
Louisville, Colorado 80027

Contact Person: Robert A. Kline
President and CEO
Telephone: 303-926-1917
Facsimile: 303-926-1924

Date Prepared: August 16, 2000

2. Device Name

Trade/Proprietary Name: Arctic Sun™ Temperature Management System, Model 100 Control Unit and Energy Transfer Pads™
Common/Usual Name: Hypo/Hyperthermia System
Classification Name: System, Thermal Regulating (per 21 CFR 870.5900)

3. Predicate Device:

The Arctic Sun™ Temperature Management System, Model 100 and patient pads, is substantially equivalent to the other thermal regulating systems on the market, such as the Allon 2001 System, manufactured by M.T.R.E Advanced Technology Ltd., Baxter Healthcare Corporation Hypo/Hyperthermia Unit, Model RK 2000 K-Thermia System, the MediTherm System, marketed by Gaymar Industries, and the Blanketrol II, TropiCool, and Norm-O-Temp Systems marketed by Cincinnati Sub-Zero.

4. Intended use of the device

The Arctic Sun Temperature Management System Model 100 is a thermal regulating system, indicated for monitoring and controlling patient temperature.

Clinical applications of this device include any condition where patient temperature control within a range covering mild hypothermia to normothermia is required. This would include, but not be limited to, medical, surgical, febrile, accidental hypothermia, or heat stroke patients.

5. Description of the Device

The Arctic Sun Temperature Management System is a device used to monitor and control patient temperature. It consists of single-use heat transfer pads, which are adhered to areas of the patient's skin, and a control module that circulates temperature-controlled water. The control module is connected to the pads by flexible tubing. A commercially available temperature probe connected to the control module senses the patient's core temperature. The system can control the patient's core temperature by altering the temperature of the circulating water.

6. Summary of the technological characteristics of the device compared to the predicate device.

The Arctic Sun Temperature Management System Model 100 and the above referenced predicate devices are thermal regulating systems as defined in 21 CFR 870.5900. These external systems consist of a device that is placed in contact with the patient and a temperature controller for the device. All these devices utilize pads, blankets or garments in contact with the patient. In all devices, the microprocessor-based temperature controllers circulate water through the pads/blankets/garments, to regulate the patient's temperature. Patient temperature is monitored in most of these devices by YSI 400 series temperature probes.

7. Testing

Testing of the Arctic Sun Temperature Management System, Model 100 Control Unit and patient pads, included biocompatibility testing in accordance with ISO 10993-1 and/or USP, electrical safety testing in accordance with IEC601 and functional safety and performance testing.

8. Conclusions

Based upon the testing and comparison to the predicate devices, the Arctic Sun Temperature Management System, consisting of the Arctic Sun™ Model 100 Control Unit and patient pads, performs as intended and raises no new safety or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 26 2000

MediVance, Inc.
c/o Mr. Robert A. Kline
President and CEO
500 S. Arthur Avenue
Suite 100
Louisville, CO 80027

Re: K002577
Trade Name: Arctic Sun™ Temperature Management System, Model 100 Control Unit and Patient Energy Transfer Pads™
Regulatory Class: II (two)
Product Code: DWJ
Dated: August 16, 2000
Received: August 18, 2000

Dear Mr. Kline:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act

obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number (if known): K002577

Device Name: Arctic Sun™ Temperature Management System, Model 100 Control Unit and patient pads

Indications For Use:

The Arctic Sun™ Temperature Management System is a thermal regulating system, indicated for monitoring and controlling patient temperature.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K002577